BRIAN M. BOYNTON, Principal Deputy Assistant Attorney General
ARUN G. RAO, Deputy Assistant Attorney General
AMANDA N. LISKAMM, Director
ALLAN GORDUS, Assistant Director
DAVID G. CROCKETT, JR., Trial Attorney (NYBN 5676192, DCBN 90002739)
ROGER GURAL, Senior Trial Attorney (GABN 300800)

U.S. Department of Justice
Civil Division
Consumer Protection Branch
450 5th Street NW, Suite 6400-S
Washington, D.C. 20530
Telephone: (202) 305-0192
David.g.crockett@usdoj.gov

Attorneys for plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, vs. CALI RICE VALLEY, INC., a corporation, AND CUONG T. DO, an individual, Defendants.	Case Number: 3:22-CV-05967-JD **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), having filed a Complaint for Permanent Injunction ("Complaint") against Cali Rice Valley, Inc., a corporation, and Cuong T. Do, an individual (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C § 332, and its inherent equitable authority.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("Act").

3. Defendants have violated 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in a manner that fails to comply with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g.

4. Defendants have violated 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health.

5. Defendants have violated 21 U.S.C. § 331(k) by causing an article of food that is held for sale after shipment of one or more of its components in interstate commerce to become

adulterated under 21 U.S.C. § 342(c) in that it bears or contains a color additive that is unsafe within the meaning of 21 U.S.C. § 379e(a).

6. Defendants have violated 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), (f), (i)(1), (i)(2), (k), or (w).

7. For the purposes of this Decree, the following definitions shall apply:

A. "Associated Persons" shall refer collectively to each and all of Defendants' directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) who are involved in manufacturing, processing, preparing, packing, labeling, holding, or distributing any article of food;

B. The "CGMP & PC Rule" shall refer to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule set forth at 21 C.F.R. Part 117;

C. "Days" shall refer to calendar days;

D. "Defendants' Facilities" shall refer to the facilities located at 3810 Delta Fair Boulevard, Antioch, California 94509, and any other location(s) at which Defendants now or in the future directly or indirectly manufacture, process, prepare, pack, label, hold, or distribute any article of food;

E. "Food Safety Expert" shall refer to an independent person (or persons) who is without any personal or financial ties (other than a retention agreement to satisfy the

requirements of this Decree or to provide food-safety consulting services prior to entry of this Decree) to Defendants or their families and who: (1) meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3 and has expert knowledge in food microbiology, product formulation, process evaluation, thermal processing, process validation, packaging, food preservation, and establishing process controls; and (2) by reason of training, education, and experience, is qualified to: (a) establish methods, processes, and controls at Defendants' Facilities to ensure that articles of food are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with the CGMP, hazard analysis, and preventive controls requirements of the Act and its implementing regulations, including the CGMP & PC Rule; (b) develop and implement written food safety plans in accordance with paragraphs 10(D) and 13(C); and (c) inspect Defendants' Facilities to determine whether Defendants' methods, processes, and controls are continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations;

F. "Labeling Expert" shall refer to an independent person (or persons) who is without any personal or financial ties (other than a retention agreement) to Defendants or their families, except that this person may be the same as the Food Safety Expert, and who, by reason of training, education, and experience, is qualified to review Defendants' product labeling to determine whether Defendants' products comply with 21 U.S.C. § 343 and all applicable regulations; and

G. "Laboratory" shall refer to an independent laboratory (or laboratories) that is without any personal or financial ties (other than a retention agreement) to Defendants or their families, and that is qualified to analyze environmental and food samples collected at

Defendants' Facilities for the presence of *Listeria* species, including *Listeria monocytogenes*, and samples of Defendants' products to verify that the finished products meet food safety specifications and critical factors (e.g., pH, water activity), in a manner acceptable to FDA.

8. Upon entry of this Decree, Defendants and all Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in a manner that fails to comply with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g;

B. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health;

C. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated under 21 U.S.C. § 342(c) in that they bear or contain a color additive that is unsafe within the meaning of 21 U.S.C. § 379e(a);

D. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343; and

E. Failing to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

9. Defendants represent that, as of February 1, 2022, they have ceased the manufacture, processing, preparing, packing, labeling, holding, and distribution of all wheat noodle products at or from Defendants' Facilities.

10. Upon entry of this Decree, Defendants and all Associated Persons who have received actual notice of this Decree are subject to the following requirements, which shall apply to the manufacture, processing, preparing, packing, labeling, holding, and distribution at or from Defendants' Facilities of all articles of food except wheat noodle products (see paragraph 13):

A. Within ten days after entry of this Decree, Defendants, at their expense, shall retain a Food Safety Expert as defined in paragraph 7(E). Defendants shall notify FDA in writing of the identity and qualifications of the Food Safety Expert within two days after retaining the Food Safety Expert;

B. Within ten days after entry of this Decree, Defendants, at their expense, shall retain a Laboratory as defined in paragraph 7(G). Defendants shall notify FDA in writing of the identity of the Laboratory within two days after retaining the Laboratory;

C. Within twenty days after entry of this Decree, Defendants shall clean and sanitize Defendants' Facilities and equipment contained therein to render the facilities and equipment suitable for receiving, manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food in accordance with this Decree, the Act, and its implementing regulations, and to ensure that Defendants' Facilities and equipment will be continuously maintained in a sanitary condition;

D. Within thirty days after entry of this Decree, Defendants shall ensure that the Food Safety Expert:

(1) Conducts a hazard analysis, which shall consider known and reasonably foreseeable hazards including, but not limited to, biological hazards (such as *Clostridium botulinum* growth and toxin formation, *Bacillus cereus* growth and toxin formation, and *Listeria monocytogenes*), chemical hazards (such as undeclared color additives, undeclared allergens, and allergen cross-contact), and physical hazards, for each product covered by paragraph 10;

(2) Develops a written food safety plan that identifies (or reviews Defendants' written food safety plan and modifies it as necessary to ensure that it identifies) the required preventive controls and establishes adequate measures to control for all hazards requiring preventive controls, consistent with the CGMP & PC Rule, and is designed to ensure that Defendants' manufacturing processes, monitoring procedures, and corrective actions protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at Defendants' Facilities. The written food safety plan shall include, but not be limited to: (a) written sanitation procedures that shall conform to the requirements in paragraph 11(A); (b) written integrated pest management procedures that shall conform to the requirements in paragraph 11(B); (c) written environmental monitoring and testing procedures that shall conform to the requirements in paragraph 11(C); and (d) written procedures for analyzing in-process and finished rice noodle products, at a minimum to monitor and test formulation critical factors (e.g., pH, water activity), that shall conform to the requirements in paragraph 11(D); and

(3) Submits the written food safety plan developed under paragraph 10(D)(2) to FDA. Thereafter, FDA will provide either a written approval of the food safety plan or a

written explanation of the food safety plan's deficiencies. If FDA requires resubmission of the food safety plan due to identified deficiencies, Defendants shall ensure that the Food Safety Expert submits the corrected food safety plan to FDA within fourteen days after receipt of the written explanation of the food safety plan's deficiencies. FDA will review the corrected food safety plan and provide written approval or further explanation of any new or remaining deficiencies. Defendants shall ensure that the Food Safety Expert responds to each written explanation of deficiencies within fourteen days after receipt of the explanation. The cycle described in this paragraph shall continue until FDA provides a written approval of the food safety plan;

E. Within fourteen days after receipt of FDA's written approval of the food safety plan under paragraph 10(D)(3), Defendants shall:

(1) Ensure that the FDA-approved food safety plan is available and accessible (in English and any other language necessary to effectively convey the substance of the documents therein) to their officers, employees, and all other persons who perform duties at Defendants' Facilities;

(2) Assign continuing responsibility for implementing and monitoring the FDA-approved food safety plan to a person(s) who, by reason of training, education, or experience, is qualified to maintain Defendants' Facilities in a sanitary condition and to coordinate and implement any necessary corrective actions, and who meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3, and Defendants provide this person with the authority and resources to achieve any necessary corrective action;

(3) Ensure that the Food Safety Expert develops a written employee training program (in English and any other language necessary to effectively convey the substance of the training) that addresses the requirements of the CGMP & PC Rule and the FDA-approved food safety plan and that includes ongoing training programs for employees; and

(4) Ensure that the Food Safety Expert submits the written employee training program developed under paragraph 10(E)(3) to FDA. Thereafter, FDA will provide either a written approval of the employee training program or a written explanation of the employee training program's deficiencies. If FDA requires resubmission of the employee training program due to identified deficiencies, Defendants shall ensure that the Food Safety Expert submits the corrected employee training program to FDA within fourteen days after receipt of the written explanation of the employee training program's deficiencies. FDA will review the corrected employee training program and provide written approval or further explanation of any new or remaining deficiencies. Defendants shall ensure that the Food Safety Expert responds to each written explanation of deficiencies within fourteen days after receipt of the explanation. The cycle described in this paragraph shall continue until FDA provides a written approval of the employee training program;

F. Within fourteen days after receipt of FDA's written approval of the employee training program under paragraph 10(E)(4), Defendants shall ensure that the Food Safety Expert: (1) trains Defendants and their employees, and all other persons who perform duties at Defendants' Facilities, in accordance with the employee training program, so that the individuals who manufacture, process, prepare, pack, label, hold, or distribute food are qualified to perform their assigned duties consistent with 21 C.F.R. § 117.4; and (2) submits documentation to FDA

demonstrating that the Food Safety Expert has adequately trained Defendants and their employees, and all other persons who perform duties at Defendants' Facilities;

G. Within thirty days after receipt of FDA's written approval of the food safety plan under paragraph 10(D)(3), Defendants shall ensure that the Food Safety Expert:

(1) In conjunction with the Laboratory, conducts environmental swabbing and testing in accordance with the environmental monitoring and testing procedures developed under paragraph 11(C) to ensure that Defendants' cleaning and sanitizing adequately address the hazard of *Listeria monocytogenes*;

(2) Conducts a comprehensive inspection of Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food, and certifies in writing to FDA: (a) that the Food Safety Expert has inspected Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food; and (b) whether Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food are, in the Food Safety Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations, including the CGMP & PC Rule; and

(3) Prepares a detailed written report, with supporting documentation, of the Food Safety Expert's inspectional findings that includes, but is not limited to: (a) the results of environmental monitoring tests; and (b) a determination of whether Defendants have implemented procedures that are adequate to ensure continuing compliance with the CGMP & PC Rule and the FDA-approved food safety plan. Defendants shall also ensure that the Food

Safety Expert submits the written certification and report with supporting documentation to Defendants and FDA concurrently, within ten days after completing the inspection;

H. Within forty-five days after entry of this Decree, Defendants, at their expense, shall retain a Labeling Expert as defined in paragraph 7(F). Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within two days after retaining the Labeling Expert;

I. Within sixty days after entry of this Decree, Defendants shall ensure that the Labeling Expert performs a comprehensive review of Defendants' labeling for rice noodle products and certifies in writing to FDA: (1) that the Labeling Expert has reviewed Defendants' labeling for rice noodle products; (2) whether Defendants have corrected all deviations from 21 U.S.C. § 343 and applicable regulations that have been brought to Defendants' attention by FDA, the Labeling Expert, and any other source; and (3) whether Defendants' rice noodle products are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. Defendants shall ensure that the Labeling Expert's written certification contains a detailed report of the Labeling Expert's review that includes, but is not limited to, samples of all reviewed product labels and all ingredient labels, and a determination of whether Defendants have implemented procedures that are adequate to ensure that their rice noodle products comply with 21 U.S.C. § 343 and all applicable regulations. Defendants shall also ensure that the Labeling Expert's written certification with supporting documentation is submitted to Defendants and FDA concurrently, within ten days after completing the labeling review; and

J. Should the Food Safety Expert's report described in paragraph 10(G)(3) or the Labeling Expert's report described in paragraph 10(I) identify any deficiencies:

(1) Within twenty days after receipt of the Food Safety Expert's report or the Labeling Expert's report, Defendants shall report in writing to FDA and the appropriate expert the actions they have taken to correct all such deficiencies;

(2) Within fourteen days after receipt of Defendants' report as described in paragraph 10(J)(1), Defendants shall ensure that the Food Safety Expert certifies in writing to FDA, based on his or her further review and/or inspection(s), whether Defendants' Facilities, methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food are, in the Food Safety Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations, including the CGMP & PC Rule;

(3) Within fourteen days after receipt of Defendants' report as described in paragraph 10(J)(1), Defendants shall ensure that the Labeling Expert certifies in writing to FDA, based on his or her further review, whether Defendants have revised the labeling to ensure that their rice noodle products are in compliance with this Decree, the Act, and its implementing regulations; and

(4) FDA will notify Defendants in writing of its evaluation of such submissions.

11. The processes, methods, and monitoring and testing procedures in Defendants' food safety plan(s) shall conform to the following requirements:

A. Defendants' written sanitation procedures shall include, but not be limited to, sanitation standard operating procedures and sanitation preventive controls for manufacturing, processing, preparing, packing, holding, and distributing articles of food, and shall, at minimum: (1) address the presence of *Listeria monocytogenes*, filth, pests, and cross-contact with food

allergens; and (2) ensure that Defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and facility construction and maintenance (including, but not limited to, buildings and sanitation-related systems, and the equipment and utensils contained therein) protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at Defendants' Facilities;

B. Defendants' written integrated pest management procedures shall include, but not be limited to, written monitoring, prevention, and control measures, and written procedures for remedial action should insects, birds, rodents, or other vermin or pests, or filth be detected;

C. Defendants shall ensure that organisms such as *Listeria species* are systemically controlled and that pathogenic organisms such as *Listeria monocytogenes* do not occur in finished products. Defendants shall conduct environmental monitoring and testing, and finished product testing, in the following manner:

(1) Defendants' environmental sampling shall be conducted according to specified frequencies and methods for how, where, and when to sample, the number and frequency of collecting samples, and the methods for analysis. Defendants shall have written procedures for: (a) collecting samples from food-contact surfaces, equipment, and other environmental sites throughout any processing areas where food is received, manufactured, processed, prepared, packed, labeled, held, or distributed, and common areas that may be reservoirs for cross-contamination; (b) analyzing samples in a manner acceptable to FDA; and (c) remedial action that Defendants shall implement should *Listeria* species or any pathogenic organism, including *Listeria monocytogenes*, be detected. The remedial action plan shall include, but not be limited to, product disposition, intensified sanitation measures, intensified

sampling and testing measures, comprehensive investigations, and contamination-source determination (i.e., a root-cause analysis);

(2) If a food-contact or non-food-contact surface tests positive for *Listeria* species during routine testing, intensified sampling and testing shall be initiated immediately, in conjunction with intensified sanitation measures. Intensified sampling requires that at least three surrounding areas (e.g., sites that are in close proximity to the positive site) are sampled during production and analyzed;

(3) Any *Listeria* species isolate from a food-contact surface shall be tested further to determine whether it is *Listeria monocytogenes*. All ready-to-eat products that come in contact with a food-contact surface that tests positive for the general strain *Listeria* species shall be held pending further testing of the *Listeria* species isolate from the food-contact surface. The held products can be released only if the *Listeria* species isolate from the food-contact surface is not *Listeria monocytogenes*. If the laboratory test result for the Listeria species isolate from the food-contact surface is positive for *Listeria monocytogenes*, Defendants shall, under FDA supervision and in accordance with a written destruction plan submitted by Defendants and approved in writing by FDA prior to implementation, destroy the held products, and recall and destroy all ready-to-eat products manufactured from the time of sampling for the last negative laboratory test results for *Listeria monocytogenes*. Defendants shall bear the costs of recall and destruction and the costs of FDA's supervision at the rates specified in paragraph 20. If any laboratory test result for a *Listeria* species isolate from a food-contact surface is positive for *Listeria monocytogenes*, Defendants shall reinstate the complete sequence of finished noodle product testing under paragraph 11(C)(4) anew;

(4) Defendants shall test all lots of finished noodle products for *Listeria monocytogenes* as follows: (a) for at least five consecutive production days, Defendants shall test all lots of finished noodle products for *Listeria monocytogenes*; (b) after the completion of testing under paragraph 11(C)(4)(a), Defendants shall randomly test at least one lot of each finished noodle product per day for the next twenty production days; (c) after the completion of testing under paragraph 11(C)(4)(b), Defendants shall randomly test at least one lot of each finished noodle product every five production days for the next three months; and (d) after the completion of testing under paragraph 11(C)(4)(c), Defendants shall test at least one lot of each finished noodle product monthly thereafter;

(5) If any finished noodle product tested pursuant to paragraph 11(C)(4) is positive for *Listeria monocytogenes*, then Defendants shall immediately cease noodle production and notify FDA that production has ceased. Defendants shall, under FDA supervision and in accordance with a written destruction plan submitted by Defendants and approved in writing by FDA, destroy all positive noodle products, as well as recall and destroy all such noodle products manufactured from the time of sampling for the last negative laboratory test results for *Listeria monocytogenes*. Defendants shall bear the costs of recall and destruction and the costs of FDA's supervision at the rates specified in paragraph 20. Defendants may resume production of noodle products only when they have determined and corrected the cause of the contamination, and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under paragraph 11(C)(4) anew; and

(6) For all tests conducted pursuant to paragraph 11(C)(4), Defendants shall ensure that all results of positive tests for the general strain *Listeria* species or *Listeria monocytogenes* are forwarded to FDA within two days after receipt by Defendants; and

D. Defendants shall have written procedures for analyzing in-process and finished noodle products that include, but are not limited to, procedures for monitoring and testing formulation critical factors (e.g., pH, water activity) of in-process and finished noodle products to ensure that finished products meet food safety specifications and critical factors identified in the food safety plan(s), and procedures for remedial action that Defendants shall implement should products be found not to meet food safety specifications or critical factors. The preventive controls implemented under this paragraph must be adequately validated to ensure that finished products meet food safety specifications and critical factors. Defendants shall conduct finished product testing for conformance to critical factors in the following manner:

(1) Defendants shall test each lot of finished noodle products identified in the food safety plan(s) as requiring formulation controls for critical factors (e.g., pH, water activity) to verify that all formulation critical factors are met; and

(2) If any finished product tested pursuant to paragraph 11(D)(1) does not meet all formulation critical factors identified in the food safety plan(s), Defendants shall notify FDA of each product failure, and provide FDA with a copy of the test results, within two days after such failure was detected. Within three days after detecting a finished product that failed to meet a formulation critical factor, Defendants shall determine and correct the cause of the deviation and notify FDA in writing of Defendants' findings and corrective action. Defendants shall, under FDA's supervision and in accordance with a written destruction plan submitted by

Defendants and approved in writing by FDA, destroy all lots of finished product that failed to meet any formulation critical factor. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 20.

12. Defendants shall continuously take the following steps to prevent the adulteration and/or misbranding of articles of food manufactured, processed, prepared, packed, labeled, held, or distributed at or from Defendants' Facilities:

A. After receipt of FDA's written approval of the food safety plan under paragraph 10(D)(3) and no later than five days after receipt of FDA's written approval of the employee training program under paragraph 10(E)(4), and again upon receipt of FDA's written notification under paragraph 13(I), Defendants shall effectively implement, on an ongoing basis, the FDA-approved food safety plan (and, if applicable, the FDA-approved food safety plan for wheat noodles), which includes, but is not limited to, the testing requirements specified in paragraphs 11(C) and 11(D);

B. Upon receipt of FDA's written approval of the employee training program under paragraph 10(E)(4), and again upon receipt of FDA's written notification under paragraph 13(I), Defendants shall effectively implement, on an ongoing basis, the FDA-approved employee training program (or, if applicable, the FDA-approved updated employee training program). The employee training program (or, if applicable, the FDA-approved updated employee training program) shall be completed by each new employee within five days after the new employee commences duties at Defendants' Facilities, and ongoing training programs for employees shall be completed in accordance with the FDA-approved employee training program (or, if applicable, the FDA-approved updated employee training program);

C. Defendants, at their expense, shall retain an independent person or persons (the "Auditor") who shall meet the criteria for, and may be the same person or persons as, the Food Safety Expert and the Labeling Expert as defined in paragraphs (7)(E) and (7)(F) to conduct audits of Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, or distribute articles of food, and of Defendants' product labeling, as follows:

(1) Defendants shall ensure that, according to the schedule in paragraph 12(C)(2), the Auditor conducts an audit of Defendants' Facilities and the methods and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food, and of Defendants' product labeling, to determine whether Defendants are operating in compliance with this Decree, the Act, and its implementing regulations, and to identify any deviations from these requirements. Defendants shall ensure that the Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within ten days after completing the audit;

(2) Upon submission of the Food Safety Expert's report to FDA under paragraph 10(G)(3) or, if that report identified any deficiencies, then upon submission of the Food Safety Expert's certification to FDA under paragraph 10(J)(2), and again upon receipt of FDA's written notification under paragraph 13(I), Defendants shall ensure that the Auditor conducts audits at least once every three months for a period of no less than one year, then at least once every six months for the next two years, and then at least annually unless FDA notifies Defendants in writing that more frequent audit inspections and reporting are required. If any Audit Report identifies any deviation from this Decree, the Act, or its implementing regulations, FDA, in its discretion, may require the audit cycle to begin anew;

(3) Defendants shall ensure that, as part of every Audit Report (except the first one), the Auditor assesses the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary; and

(4) Defendants shall ensure that, within twenty days after the required completion date for any corrective action under paragraph 12(C)(3), the Auditor reviews each and all corrective action(s) taken by Defendants and reports in writing to FDA whether each deviation listed in the Audit Report has been corrected;

D. In the event that Defendants change their manufacturing location and/or the Food Safety Expert or the Auditor determines that the FDA-approved food safety plan or the FDA-approved food safety plan for wheat noodles needs to be revised, Defendants shall:

(1) Ensure that the Food Safety Expert or Auditor reviews the proposed changes and certifies in writing to FDA that the proposed changes establish methods, processes, and controls at Defendants' Facilities to ensure that articles of food are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, and implementing regulations, including the CGMP & PC Rule; and

(2) Ensure that the Food Safety Expert's or Auditor's written certification with supporting documentation is submitted to Defendants and FDA concurrently,

within five days after completing the review, and at least twenty days prior to the planned implementation. Defendants shall not implement the proposed changes unless and until FDA approves those changes in writing; and

E. If, after notifying FDA of the name of the Laboratory retained to conduct analyses pursuant to paragraph 10(B) or 13(B), Defendants terminate their service contract with the Laboratory, Defendants shall notify FDA within two days after terminating the service contract. Within five days after terminating the service contract, Defendants shall retain a replacement laboratory that meets the qualifications of the Laboratory as defined in paragraph 7(G), and Defendants shall notify FDA in writing of the identity of the replacement laboratory within two days after retaining the laboratory.

13. Upon entry of this Decree, Defendants and all Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court from directly or indirectly manufacturing, processing, preparing, packing, labeling, holding, and distributing any wheat noodle product at or from Defendants' Facilities unless and until:

A. Defendants, at their expense, retain a Food Safety Expert as defined in paragraph 7(E), who can be the same person retained under paragraph 10(A). Defendants shall notify FDA in writing of the identity and qualifications of the Food Safety Expert within two days after retaining the Food Safety Expert;

B. Defendants, at their expense, retain a Laboratory as defined in paragraph 7(G), which can be the same laboratory retained under paragraph 10(B). Defendants shall notify FDA in writing of the identity of the Laboratory within two days after retaining the Laboratory;

C. Defendants ensure that the Food Safety Expert:

(1) Evaluates Defendants' wheat noodle products to review product formulations (including, but not limited to, product specifications, pH, water activity, ingredients, and allergens), processing operations (including, but not limited to, soaking, thermal processing, holding, and time and temperature controls), packaging (including, but not limited to, materials, packaging conditions, and reduced oxygen packaging), shelf-life, and storage and distribution conditions (including, but not limited to, time and temperature controls); and prepares a written report that contains a detailed description of Food Safety Expert's findings. Defendants shall ensure that the Food Safety Expert's product evaluation is submitted to Defendants and FDA concurrently, within ten days after completing the product evaluation;

(2) Conducts a hazard analysis, which shall consider known and reasonably foreseeable hazards including, but not limited to, biological hazards (such as *Clostridium botulinum* growth and toxin formation, *Bacillus cereus* growth and toxin formation, and *Listeria monocytogenes*), chemical hazards (such as undeclared color additives, undeclared allergens, and allergen cross-contact), and physical hazards, for Defendants' wheat noodle products;

(3) Develops a written food safety plan for Defendants' wheat noodle products that identifies the required preventive controls and establishes adequate measures to control for all hazards requiring preventive controls, consistent with the CGMP & PC Rule, and is designed to ensure that Defendants' manufacturing processes, monitoring procedures, and corrective actions protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at Defendants' Facilities. The food safety plan for wheat noodles shall include, but not be limited to: (a) written sanitation procedures that shall conform to the

requirements in paragraph 11(A); (b) written integrated pest management procedures that shall conform to the requirements in paragraph 11(B); (c) written environmental monitoring and testing procedures that shall conform to the requirements in paragraph 11(C); and (d) written procedures for analyzing in-process and finished wheat noodle products, at a minimum to monitor and test formulation critical factors (e.g., pH, water activity), that shall conform to the requirements in paragraph 11(D):

(4) Updates the FDA-approved employee training program (in English and any other language necessary to effectively convey the substance of the training) so that it addresses the requirements of the food safety plan for wheat noodles approved by FDA under paragraph 13(D);

(5) Submits the written food safety plan for wheat noodles developed under paragraph 13(C)(3) and the updated employee training program developed under paragraph 13(C)(4) to FDA;

(6) Trains Defendants and their employees, and all other persons who perform duties at Defendants' Facilities, in accordance with the updated employee training program approved by FDA under paragraph 13(D), to ensure that the individuals who manufacture, process, prepare, pack, label, hold, or distribute food are qualified to perform their assigned duties consistent with 21 C.F.R. § 117.4. Defendants shall ensure that the Food Safety Expert submits documentation to FDA demonstrating that the Food Safety Expert has adequately trained Defendants and their employees, and all other persons who perform duties at Defendants' Facilities;

(7) In conjunction with the Laboratory, conducts environmental swabbing and testing in accordance with the FDA-approved food safety plan for wheat noodles to ensure that Defendants' cleaning and sanitizing adequately address the hazard of *Listeria monocytogenes*;

(8) Conducts a comprehensive inspection of Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food; and

(9) Certifies in writing to FDA that: (a) the Food Safety Expert has evaluated the results of product formulation and environmental monitoring tests, and inspected Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food; and (b) Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food are, in the Food Safety Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations, including the CGMP & PC Rule. Defendants shall ensure that the Food Safety Expert's written certification contains a detailed report of the Food Safety Expert's inspectional findings that includes, but is not limited to, the results of product formulation and environmental monitoring tests and a determination that Defendants have implemented procedures that are adequate to ensure continuing compliance with the CGMP & PC Rule and the FDA-approved food safety plan for wheat noodles. Defendants shall also ensure that the Food Safety Expert's written certification with supporting documentation is submitted to Defendants and FDA concurrently, within ten days after completing the inspection;

D. FDA has approved, in writing, the food safety plan for wheat noodles and the updated employee training program submitted under paragraph 13(C)(5);

E. Defendants: (1) ensure that the FDA-approved food safety plan for wheat noodles is available and accessible (in English and any other language necessary to effectively convey the substance of the documents therein); and (2) assign continuing responsibility for implementing and monitoring the FDA-approved food safety plan for wheat noodles to a person(s) who, by reason of training, education, or experience, is qualified to maintain Defendants' Facilities in a sanitary condition and to coordinate and implement any necessary corrective actions, and who meets the requirements of a preventive controls qualified individual as defined in 21 C.F.R. § 117.3, and Defendants provide this person with the authority and resources to achieve any necessary corrective action;

F. Defendants, at their expense, retain a Labeling Expert as defined in paragraph 7(F) who can be the same person retained under paragraph 10(H). Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within two days after retaining the Labeling Expert;

G. Defendants ensure that the Labeling Expert performs a comprehensive review of Defendants' labeling for wheat noodle products and certifies in writing to FDA that: (1) the Labeling Expert has reviewed Defendants' labeling for wheat noodle products; (2) Defendants have corrected all deviations from 21 U.S.C. § 343 and applicable regulations that have been brought to Defendants' attention by FDA, the Labeling Expert, and any other source; and (3) Defendants' wheat noodle products are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. Defendants shall ensure that the Labeling Expert's written certification contains a detailed report of the Labeling Expert's review that includes, but is not limited to, samples of all reviewed product labels and all ingredient labels,

and a determination that Defendants have implemented procedures that are adequate to ensure that their wheat noodle products comply with 21 U.S.C. § 343 and all applicable regulations. Defendants shall also ensure that the Labeling Expert's written certification with supporting documentation is submitted to Defendants and FDA concurrently, within ten days after completing the labeling review;

H. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' Facilities, including the buildings, sanitation-related systems, equipment, utensils, and all articles of food and relevant records contained thereinto, to evaluate whether Defendants are in compliance with the requirements of this Decree, the Act, and its implementing regulations; and

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 13(A)–13(G) of this Decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

14. Nothing in paragraph 13 precludes Defendants from manufacturing, processing, preparing, packing, labeling, holding, or distributing any wheat noodle product for the sole purpose of performing validation studies (e.g., to validate product formulations or thermal processes), provided, however, that the wheat noodle products produced pursuant to this paragraph shall not be distributed commercially, i.e., to any distributor, customer, or consumer. Within thirty days after validation studies are completed, Defendants shall destroy all wheat noodle products produced pursuant to this paragraph and provide written documentation to FDA that such destruction has been completed. Defendants shall maintain in a separate file at

Defendants' Facilities a written log of all lot numbers of wheat noodle products produced under this provision and shall immediately make the written log available to FDA upon request.

15. Immediately after receipt of written notification from FDA under paragraph 13(I), Defendants shall be subject to all the requirements set forth in paragraph 12.

16. If, at any time after this entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, report or data prepared or submitted by Defendants, the Food Safety Expert, the Labeling Expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action including but not limited to ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, and distributing any and all articles of food;

B. Recall, at Defendants' expense, any and all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers that in FDA's judgment are adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants shall, under FDA supervision, destroy all articles of food that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall not dispose of any article of food in a manner contrary to the provisions of the Act, any other federal law, any court order, or the laws of any state or

Territory, as defined in the Act, in which the articles of food are disposed. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 20;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Submit samples to a qualified laboratory for analysis;

F. Institute or reimplement any of the requirements set forth in this Decree;

G. Issue a safety alert; and

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

Any cessation of operations or other action described in this paragraph shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. In no circumstance shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, investigations, supervision, examinations, sampling, testing, analyses, travel time, and subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in paragraph 20. These remedies shall be separate and

apart from, and in addition to, any other remedies available to the United States under this Decree or the law.

17. If FDA issues a directive pursuant to paragraph 16, the following process and procedures shall apply:

A. Unless a different time frame is specified by FDA in its directive, within seven days after receiving such directive, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement and, in doing so, may provide specific alternative actions and time frames for achieving FDA's objectives. After receipt of Defendants' notification and explanation, FDA will review Defendants' notification and explanation and, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's affirmed or modified directive, immediately implement it, and may, if Defendants so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to implement and fully comply with FDA's directive, unless and until the Court stays, reverses, or modifies FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 26; and

B. The process and procedures in paragraph 17(A) shall not apply to any directive issued pursuant to paragraph 16 if such directive states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such directive, immediately and fully comply with the terms of that directive, and the directive shall be a final agency decision. Should Defendants seek to challenge any such directive, they may petition the Court for relief while they implement FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 26.

18. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facilities, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA representatives shall be permitted immediate access to Defendants' Facilities and other place(s) of business, including but not limited to all buildings or other structures, equipment, raw ingredients, in-process or unfinished and finished materials and products, packaging, labeling, and manufacturing and processing activities; to take photographs and make video recordings; to take samples, without charge to FDA, of Defendants' raw ingredients, finished and unfinished materials and products, packaging, and labeling; and examine and copy all records relating to the receipt, manufacture, processing, preparing, packing, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

19. Defendants shall promptly provide any information or records to FDA upon request regarding the manufacture, processing, preparing, packing, labeling, holding, and distribution of Defendants' products. Defendants shall maintain copies of the food safety plan (and, as applicable, the food safety plan for wheat noodles) along with copies of all records required by these plans and this Decree at Defendants' Facilities, in a location where the records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three years after the date the records are prepared.

20. Defendants shall pay all costs of FDA's inspections, investigations, supervision, examinations, sampling, testing, analyses, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including all travel expenses and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment to FDA within thirty days after receiving an electronic invoice for payment, which shall be sent to cuongdo111@yahoo.com. Defendants shall make payment thorough the pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date of entry of this Decree, these rates are: $110.59 per hour or fraction thereof per representative for inspection and investigative work; $132.56 per hour or fraction thereof per representative for analytical or review work; $0.65 per mile (plus tolls) for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. If the email

address at which Defendants receive electronic invoices changes, Defendants shall notify FDA within twenty days of such change.

21. Within ten days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' Facilities and at any other location at which Defendants conduct business and shall ensure that this Decree remains posted for as long as this Decree remains in effect. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts therein, stating the fact and manner of compliance with this paragraph.

22. Within ten days after entry of this Decree, Defendants shall provide a copy of this Decree by personal service or certified mail (return receipt requested) to each and all Associated Persons. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts therein, stating the fact and manner of compliance with this paragraph, including identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree pursuant to this paragraph.

23. Within ten days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree, either in person or via video conference or webinar. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts therein, stating the fact and manner of compliance with this paragraph.

24. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall, within ten days after the commencement of such association, provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such Associated Person(s); and provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts therein, stating the fact and manner of compliance with this paragraph, including identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph.

25. Defendants shall notify FDA in writing at least twenty days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Cali Rice Valley, Inc., or the sale or assignment of any business assets, such as Defendants' Facilities, and other buildings or structures, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least thirty days prior to any such sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than twenty days prior to any change in ownership, sale, or assignment.

26. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any

FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

27. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: four thousand dollars ($4,000) in liquidated damages for each day such violation continues; an additional sum of three thousand dollars ($3,000) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. The liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

28. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

29. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to Program Division Director, Office of Human and Animal Food Operations West 5 (HAFW 5), San Francisco District Office, U.S. Food and Drug Administration, 1201 Harbor Bay Parkway,

Alameda, CA 94502, with a copy to ORAHAFWEST5FirmResponses@fda.hhs.gov, and shall reference this civil action by case name and civil action number.

30. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

31. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

CUONG T. DO
Individually and on behalf of
CALI RICE VALLEY, INC.

GEORGE C. SALMAS
MICHAEL R. HAMBLY
The Food Lawyers
1880 Century Park East, Suite 611
Los Angeles, CA 90067
310-556-0721
george.salmas@thefoodlawyers.com
michael.hambly@thefoodlawyers.com

ARTHUR J. LIU
Inter-Pacific Law Group, Inc.
324 10th Street, Suite 223
Oakland, CA 94612
510-986-1198
arthurliuusa@yahoo.com

Attorneys for Defendants

For Plaintiff

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director
Consumer Protection Branch

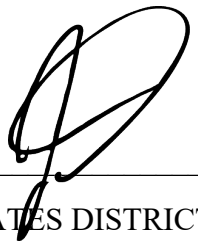
DAVID G. CROCKETT, JR.
Trial Attorney
ROGER GURAL
Senior Trail Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-305-0192
david.g.crockett@usdoj.gov

OF COUNSEL:
MARK RAZA
Chief Counsel
Food and Drug Administration

SHANNON M. SINGLETON
Acting Deputy Chief Counsel, Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
claudia.zuckerman@fda.hhs.gov

IT IS SO ORDERED, this 19th day of December, 2023.



UNITED STATES DISTRICT JUDGE